(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

§ 522.540 Dexamethasone solution.

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061, 000859, and 061623 for use as in paragraph (a)(3) of this section.

(ii) *Sponsors.* See Nos. 054925 and 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use*—(i) *Amount.* The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

(2) *Sponsor.* See number in § 510.600(c) of this chapter as follows:

(i) No. 061623 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(ii) No. 000402 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(3) *Conditions of use*—(i) *Amount.* Administer 0.25 to 1 mg by intravenous injection, repeated for 3 to 5 days or until a response is noted.

(ii) *Indications for use.* For use in dogs for the treatment of inflammatory conditions, as supportive therapy in canine posterior paresis, as supportive therapy before or after surgery to enhance recovery of poor surgical risks, and as supportive therapy in nonspecific dermatosis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

(2) *Sponsor.* See Nos. 000402 and 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer 2.5 to 5.0 mg by intravenous injection.

(ii) *Indications for use.* For use in horses as a rapid adrenal glucocorticoid and/or anti-inflammatory agent.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

(2) *Sponsors.* See the following numbers in § 510.600(c) of this chapter:

(i) Nos. 000859 and 054771 for intravenous or intramuscular use of 2.0 milligrams dexamethasone injection.

(ii) No. 054771 for intravenous use of 2.0 milligrams dexamethasone injection.

(3) *Conditions of use*—(i) *Amount.* Administer by intravenous or intramuscular injection as follows:

(A) *Dogs:* 0.25 to 1 mg.

(B) *Cats:* 0.125 to 0.5 mg.

(C) *Horses:* 2.5 to 5 mg.

(ii) *Indications for use.* For use in dogs, cats, and horses as an anti-inflammatory agent.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of solution contains 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

(2) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Administer by intravenous injection as follows:

(A) *Dogs:* 0.25 to 1 mg; may be repeated for 3 to 5 days.

(B) *Horses:* 2.5 to 5 mg.

(ii) *Indications for use*. For use in dogs and horses for glucocorticoid and anti-inflammatory effect.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 522.542 Dexamethasone suspension.

(a) *Specifications*. Each milliliter of suspension contains 1 milligram (mg) of dexamethasone-21-isonicotinate.

(b) *Sponsor*. No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer by intramuscular injection as follows: Dogs: 0.25 to 1 mg; cats: 0.125 to 0.5 mg; horses: 5 to 20 mg. Dosage may be repeated.

(2) *Indications for use*. For the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

§ 522.558 Dexmedetomidine.

(a) *Specifications*. Each milliliter of solution contains 0.1 or 0.5 milligrams dexmedetomidine hydrochloride.

(b) *Sponsor*. See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use and amount*. (A) For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures, administer 375 micrograms (µg) per square meter (/m^2) of body surface area by intravenous injection or 500 µg/m^2 of body surface area by intramuscular injection.

(B) For use as a preanesthetic to general anesthesia, administer 125 µg/m^2 of body surface area or 375 µg/m^2 of body surface area by intramuscular injection.

(ii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 40 µg/killogram by intramuscular injection.

(ii) *Indications for use*. For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures; and as a preanesthetic to general anesthesia.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 263, Jan. 4, 2007, as amended at 72 FR 19797, Apr. 20, 2007; 72 FR 51365, Sept. 7, 2007; 75 FR 60308, Sept. 30, 2010; 78 FR 25183, Apr. 30, 2013; 78 FR 33699, June 5, 2013]

§ 522.563 Diatrizoate.

(a) *Specifications*. Each milliliter of solution contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. For excretion urography, administer 0.5 to 1.0 milliliter (mL) per pound of body weight to a maximum of 30 mL intravenously. For cystography, remove urine, administer 5 to 25 mL directly into the bladder via catheter. For urethrography, administer 1.0 to 5 mL via catheter into the urethra to provide desired contrasts delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 mL directly into the heart via catheter or intraventricular puncture. For cerebral angiography, rapid injection of 3 to 10 mL via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography, rapidly inject 3 to 10 mL intravascularly into the vascular bed to be delineated. For lymphography, slowly inject 1.0 to 10 mL directly into the lymph vessel to